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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,279	01/13/2004	Mohamed Kheir Diab	MASIMO.004C4	4309

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EXAMINER
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BERHANU, ETSUB D

ART UNIT	PAPER NUMBER
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3768

NOTIFICATION DATE	DELIVERY MODE
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04/01/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,279	<b>Applicant(s)</b> DIAB ET AL.	
	<b>Examiner</b> ETSUB D. BERHANU	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/13/04 6/13/05 5/15/06</u> .                                 | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 43-49, 51-56, 58-77 and 79-82 are objected to because of the following informalities: line 1 of each claim should be amended to delete a "Claim" term. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 68, 71 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Specification of the current invention fails to disclose an information element comprising an encrypted element or information usable to identify a type of patient, wherein the type of patient includes an indication of a condition of the patient.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 44-48, 52-56, 58-60 and 75-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 44-48, 52-56, 58-60 and 75-77 fail to provide further structural limitations to the current invention, and are therefore indefinite. Regarding claims 44 and 52, a timing signal is not a structural element and therefore provides no

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further structural limitations to the claimed invention. Regarding claims 45 and 53, a threshold is a value, not a structural element, and a probe signal is not a structural element, and therefore, neither of these elements provides a further structural limitation to the claimed invention. Regarding claims 58 and 59, these claims recite an intended use of the signal line and information element, but fail to provide further structural limitations to the current invention. Claims 60 and 75 place further limitations on an LED drive signal and probe signal, but no structural limitations on the claimed invention. It is further noted that claim 75 discloses an intended use for the signal line. Claims 78-80 are drawn to a method of communicating with a physiological monitor, but fail to positively recite method steps wherein communication with a physiological monitor takes place. As such, the scope of the positively claimed steps is not consistent with the preamble.

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 78-82 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 78 does not result in a physical transformation nor does it appear to provide a useful, concrete and tangible result. Specifically, it does not appear to produce a tangible result because merely communicating with a physiological monitor is nothing more than the transfer of data. It fails to use or make available for use the result of the communication to enable its functionality and usefulness to be realized. Therefore, claims 78-82 appear non-statutory.

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***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 42, 43, 45-51, 53-79, 81 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaestle'588 (cited by Applicant).

Figure 5 of Kaestle'588 discloses a system for monitoring a physiological parameter of a patient (see TITLE), the system comprising: a physiological sensor 21 operable to detect a physiological parameter, LED circuitry 30, 31 in communication with a drive signal line and which operate in response to an LED drive signal comprising a voltage on the drive signal line (coding element 46 → multiplexer 37 → comparator 39 → microprocessor 45 → digital-to-analog converter 32 → led driver circuits 30, 31 → LEDs 22-25), an information element 46 operable to provide information data on the drive signal line, a physiological monitor/processor 33 which provides the drive signal and receives the information data from the information element, and a connector (cable disclosed in col. 5, lines 38-40) operable to provide communication between the information element and signal line (see description of Figure 5). Kaestle'588 discloses that the information element comprises either a passive element, a coding resistor, an impedance device, an active element, an active circuit or a memory chip (col. 3, lines 21-27), wherein the information provided by the information element comprises identification data such as coded/encrypted probe data to identify a probe as an adult probe or a pediatric probe (col. 3, lines 5-13 and col. 7 lines 22-25), which is also usable to identify a type of patient (adult or neonate), coded/encrypted data pertaining to the characteristics of the LED drive signal such as operating wavelengths of the LEDs (col. 1, lines 41-46 and col. 6, line 62 – col. 7, line 3). Regarding claims 45, 53 and 75, it is well known in the art that in order to turn an LED on, a

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minimum amount of current or voltage must be provided to the LED, and therefore, a threshold value must inherently be surpassed by the drive signal in order to turn the LEDs on. It is also noted that the system is capable of receiving a probe signal less than a predetermined threshold. Regarding claims 46-48, 54-56, 60, 76 and 77, it is noted that in disclosing that an exciting current is provided to the LEDs (col. 5, lines 63-66), Kaestle'588 also discloses that the threshold and probe signal comprise a voltage signal. As is well known in the art, current, according to Ohm's Law, is voltage divided by resistance, so in order for a current signal to be supplied, a voltage signal must inherently be present. Regarding claim 72, the information provided by the information element is used to determine an oxygen saturation level of the patient, and is therefore capable of identifying a type of patient (a patient with a normal oxygen saturation level vs. a patient with a low oxygen saturation level). Kaestle'588 also discloses a method of using the system described above to communicate with a physiological monitor, wherein the method comprises providing the information element in communication with a signal line, providing LED circuitry in communication with the signal line and receiving a drive signal provided by a processor in response to information data (see description of Figure 5). Regarding claim 58, the signal line to the LED driver circuit receives an LED drive signal to drive the LEDs once the information element has already provided information to the physiological monitor. The information element provides information to the physiological monitor before the LED drive signal is received. Regarding claim 59, the signal line does not receive an LED drive signal at a level to sufficiently drive an LED until the information element has provided information to the physiological monitor.

10. Claims 42-60, 64-68 and 71-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakai et al.'877 (cited by Applicant).

Figure 1 of Sakai et al.'877 discloses a system for monitoring a physiological parameter of a patient (see TITLE), the system comprising: a physiological sensor 3 operable to detect a

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physiological parameter, LED circuitry 19 in communication with a drive signal line and which operates in response to an LED drive signal comprising a voltage on the drive signal line (memory 56 → cpu 10 → LED circuitry 19 → LEDs 20, 21), an information element 56 with encoded data operable to provide information data on the drive signal line (see Figure 4 and description thereof), a physiological monitor/processor 10 which provides the drive signal and receives the information data from the information element, and a connector (col. 3, lines 13-15) operable to provide communication between the information element and signal line (see description of Figure 1). Sakai et al.'877 further discloses a timing signal wherein the LED circuitry is in communication with the signal line in response to the timing signal (col. 5, lines 53-60). Regarding claims 45, 53 and 75, it is well known in the art that in order to turn an LED on, a minimum amount of current or voltage must be provided to the LED, and therefore, a threshold value must inherently be surpassed by the drive signal in order to turn the LEDs on. It is also noted that the system is capable of receiving a probe signal less than a predetermined threshold. Figure 5 and col. 5, line 65 - col. 6, line 4 disclose that the LED drive signal comprises a voltage signal as does a probe signal. Regarding claims 71 and 72, the information provided by the information element is used to determine an oxygen saturation level of the patient, and is therefore capable of identifying a type of patient (a patient with a normal oxygen saturation level vs. a patient with a low oxygen saturation level). The information element is also capable of providing information relating to the operating wavelength of at least one LED (see Figure 4 and description thereof). Sakai et al.'877 also discloses a method of using the system described above to communicate with a physiological monitor, wherein the method comprises providing the information element in communication with a signal line, providing LED circuitry in communication with the signal line and receiving a drive signal provided by a processor in response to information data (see description of Figure 1 and col. 8, line 67 – col. 9, line 36). Regarding claim 58, the signal line to the LED driver circuit receives an LED drive signal to

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drive the LEDs once the information element has already provided information to the physiological monitor. The information element provides information to the physiological monitor before the LED drive signal is received. Regarding claim 59, the signal line does not receive an LED drive signal at a level to sufficiently drive an LED until the information element has provided information to the physiological monitor.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768

EDB